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SUBJECT: A CHRONOLOGY OF THE AMENDMENTS PROPOSED FOR THE BIRD SHIELD® LABEL, TRACKING NO. 192565

The data package dated March 27, 2003, with the Tracking No. 192565, specifically requests that Worker Health and Safety (WHS) Branch reconsider the Bird Shield® product's additional uses on rice and apples. Bird Shield (EPA Reg. No. 66550-1), which is distributed by Bird Shield Repellent Corporation, is a bird repellent concentrate containing 26.4% (by weight) of methyl anthranilate (MA) as the active ingredient (AI). The undated, unsigned request instructions for reconsideration were from the registration specialist Gary Sprock, who asked specifically that the re-evaluation be based on the master label stamp dated October 31, 2002 by the U.S. Environmental Protection Agency (U.S. EPA), and be limited to the uses on rice and apples (as so reflected in the subject line of his request). Since March 2003, WHS has been provided with two additional versions of the master label for the reconsideration. The following chronology, along with some brief commentaries, is submitted here to highlight the complexity and the critical issues involved. These commentaries and the chronology are also intended for use as a reference to facilitate the completion of the aforesaid reconsideration.

WHS' review of insignificant exposure for Bird Shield dates back to May 1999. At that time, the uses of this bird repellent were limited to grapes, cherries, turf, and various non-fishbearing bodies of water (Dong, 1999a, 1999b). With some mitigation measures proposed and later implemented, such as extended pre-harvest intervals (PHI) and additional personal protective equipment, the worker exposures from these uses were considered to be insignificant.

In November 2001, WHS further reviewed the additional uses of Bird Shield on sunflowers, corn, and bird nests (Dong, 2001). Based on the labeling for application directions and the default assumptions in place for calculation of the reentry exposure at that time, the worker exposures from these additional uses were also considered to be insignificant.

The first time at which WHS reviewed the additional uses on rice (including wild rice) and apples was April 23, 2002 (Dong, 2002). Both the handler and the reentry exposures from use on apples were concluded to be insignificant in that 2002 review, as the exposure scenario for use on this pome fruit was considered comparable to those for uses on cherries and table grapes. On the other hand, primarily due to the lack of knowledge about the cultural practice involved, at that time no conclusion was reached for the use on rice (and wild rice). The 2002 review was based on the label amendment dated January 9, 2002. As stated earlier, the label amendment

included in the data package for *reconsideration* was dated *October 31, 2002*. The two additional versions provided after the submission of the data package for reconsideration were stamped April 14, 2003 by the U.S. EPA, and dated May 2, 2003 by the registrant specialist.

As acknowledged frankly in some of the earlier reviews, the active ingredient MA can be found in grapes, some cough medicines, some other fruits, and some natural foods. Nevertheless, this series of reviews works on the premise that MA's natural occurrence level (NOL) in the general population can serve as a safe dose level only, whereas a dose *substantially* above the NOL cannot be deemed as insignificant in that there are no chemical-specific toxicity data available to determine the (critical) no adverse effect level. Furthermore, here the reviews all work on the principle that if there are residues on crops at sufficient concentrations to repel birds, then these residues could well be high enough for dermal uptake by harvesters or handlers. Whether or not the daily (or seasonal) dermal uptake by certain worker groups would significantly surpass the daily (or seasonal) NOL is actually the matter of concern here. As for all similar uses, the concerns here are primarily with the exposures of two worker groups: the handlers and the fieldworkers.

Upon an extensive (to the extent feasible) review of the various versions of the label amendment provided to WHS, the assessor noticed numerous inconsistencies that could have a significant impact on the conclusions (to be) drawn in both the previous evaluations and the present reconsideration. These issues, while they may not be all necessarily exhaustive at this point due to the complexity involved, are summarized (and in many cases italicized) as follows.

<u>Use on Cherries</u>
Prior to the subject master label dated (proposed) October 31, 2002, the maximum application rate for cherries was restricted to 2.29 lb AI per acre. Since then, that rate restriction has been lifted and hence by default the maximum rate for ground application to cherries is now 6.18 lb AI/acre. The mitigation measures proposed (Dong, 1999a) for the use on this crop were *both* a maximum rate of 3.0 lb AI/acre *and* a PHI of 9 days. The maximum rate should be as low as 2.29 lb AI/acre since the recent amendments all insist on a PHI of as early as 5 days. *In short, the re-revised higher application rate now reverts to a potential significant reentry exposure for cherry harvesters.*

<u>Use on Blueberries</u>
The use on blueberries in California has been added since the master label amended January 9, 2002. According to all amendment versions since that date, the maximum label rate for this crop is 2.29 lb AI per acre, with a default (i.e., non-crop specific) PHI of 5 to 8 days. *At this maximum rate, the reentry exposure for blueberry hand harvesters would be significant if the dislodgeable foliar residues (DFR) on this crop had a half-life longer than those on cherries*. It is of note that the label rate for table grapes is limited to 1.15 lb AI/acre, in line with the fact that the DFR on table grapes were shown experimentally (by the registrant) to have a longer half-life than those on cherries.

Use on Stone Fruit/Berries

It is unclear from the two most recent amendment versions, whether or not in California the uses on other berries (e.g., raspberries) and other stone fruit (e.g., nectarine) are excluded. *Otherwise, similar concerns should be raised regarding the maximum label rate and the DFR dissipation behavior for each crop included in these two groups*.

Use on Sweet Corn

The dermal transfer rate assumed earlier for corn hand harvesters (Dong, 2001) was about 2- to 3-fold lower than the default rate now in place. Even with the use of the higher transfer rate, the reentry exposure for corn (hand) harvesters could still be considered marginally insignificant *provided that ground application is prohibited and that the DFR on corn do not have a half-life substantially longer than those on table grapes*. Given that the maximum label rate for table grapes is 1.15 lb AI/acre by ground, which is about *4 times higher* than that for sweet corn by air (0.28 lb AI/acre), the reentry exposure for corn harvesters should still be considered marginally insignificant even when the 3-fold higher dermal transfer rate were used. Such an expectation has taken into account that the DFR on corn might even have a half-life a bit longer than those on table grapes. Also, it appears that the two most recent amendment versions allow only 2 applications to sweet corn per season, with both the PHI and the reapplication interval being 5 days. Nonetheless, the two most recent amendment versions specify that instructions for aerial application be followed for cereal grains under which sweet corn is listed. There is no mention of ground application. *Therefore, in the absence of a specified prohibition, ground application must be assumed permissible for sweet corn*. And the default maximum label rate (6.18 lb AI/acre) for ground application is 22 times, rather than 4 times, higher than that for aerial.

Uses on Cereal Grains

The two most recent versions of the label amendment (i.e., those dated April and May, 2003) lists rice and corn under this cereal grains group without specifically excluding other cereal grains. Therefore, uses on other cereal grains must be assumed here. This concern has much to do with the greater potential for farmers to practice the intercropping principles, on which farmers are usually left with the option of hand harvesting crops one by one (for fear of having those others nearby damaged by mechanical harvesters). Reentry exposure for fieldworkers is typically estimated from multiplying the DFR projected for the day of reentry by a pre-determined dermal transfer rate. *Since both parameters are primarily crop-specific*, the other cereal grains not excluded must be identified first. Chemical- and crop-specific data on DFR must then be available or at least approximated, before potential reentry exposure can be assessed fairly for workers harvesting each of those other cereal grain crops.

Ornamentals

The use on ornamentals in California was not included until the version dated April, 2003. It is then excluded in the latest version dated May, 2003, which unlike the earlier April version has not yet been stamp approved by the U.S. EPA. The concern here is that *there is no information regarding the PHI or reapplication intervals for this crop group. The DFR on ornamentals*

potentially could have a half-life even longer than those on table grapes, especially for those ornamentals grown in greenhouses. If the use on ornamentals is to stay, then chemical- and crop-specific data on DFR are required in addition to the information on PHI and reapplication intervals. Without these information and data, it will be impossible to perform a fair assessment of the potential reentry exposure for the ornamental harvesters.

Use on Apples

Despite the fact that reentry exposure was concluded previously (Dong, 2002) to be insignificant for apple harvesters, the same conclusion cannot be made now for the use specified in the two most recent amendment versions. The maximum ground application rate for apples has now been lifted from 1.15 lb AI/acre and defaulted to the maximum rate of 6.18 lb AI/acre. *This rate increase simply outpaces substantially the difference between the lower dermal transfer rate assumed for apple harvesters (4,000 μg AI/hour per μg/cm^2 of DFR) and the higher rate assumed for table grape harvesters (7,500)*.

Seed Treatment for Rice

The two latest amendment versions specify that the imbibed seed be coated with a 25% solution of repellent concentrate. *Such labeling falls short of providing the assessor with the information required to estimate a reasonable maximum amount of the bird repellent AI handled daily in a seed treatment facility or at the site of operation*. Workers may be subject to inhalation and dermal exposures while being around the seed treatment site. The premise here is that worker exposures of this type are primarily a function of the amount of chemical handled. Branch staff previously considered the occupational exposures to be quite serious for handlers working in seed treatment facilities (Dong, 1996; Formoli, 1991, 1993; Haskell, 1994). Therefore, without the information on daily use in a seed treatment facility, it will be impossible to assess fairly the potential exposure for these handlers.

Use on Rice

There are now apparently sufficient literature and documents confirming that rice and wild rice in California are harvested mechanically using a combine. In addition, the use on rice in a small scale operation, such as those for research purposes or the kind, is unlikely to involve hand harvesting, if any, for any considerable exposure duration. However, the bird repellent is nonetheless allowed to be applied to rice and wild rice as often as 5 or 6 times before harvest, at a reapplication interval of as early as 5 days. While the PHI is 5 days, it is unclear what the built-up residue level on or in rice may be after several reapplications made at close intervals. Even though the hulls to which any of the repellent is applied will be removed, such removal may not be 100% and some contamination can take place easily. Rice is not steam cleaned or pre-cooked in all cases. During cooking, rice is often kept inside a cooker with a lid on. There are people eating 4 or more bowls of rice a day in California as well as in some other parts of the country. Otherwise, rice growing might not have been such a big business in California. *In short, it is not sure if dietary exposure can be considered as very limited or non-existent.*

Reapplication Interval

In a couple of places, the label instructions for reapplication are unnecessarily redundant or somewhat confusing, even to the point that growers may apply the bird repellent more often than allowed to. For example, the instruction '*Reapply every 5 to 8 days if birds reapear*' runs unnecessarily with '*Repeat as necessary to maintain repellency*'. Or the instruction '*Begin application 10 days before harvest . . .*' is followed immediately by '*Reapply at 5-day intervals until harvest*' and '*Harvest 5 days after last treatment*'.

Mixer/Loader Exposure

The mixer/loader exposure to MA now cannot be considered insignificant for rice, sunflowers, *sweet corn, and any other crops that are subject to aerial application*. Earlier versions of the master label require that mixer/handlers (including airblast applicators) wear coveralls over normal work clothes, and not prepare spray solutions with more than 50 gallons of the concentrate (i.e., not more than 114.5 lb AI in total, or 409 acres at the maximum aerial rate of 0.28 lb AI/acre) per day. Yet as written now, such a usage restriction has not been extended to aerial application. And a single aerial application can easily involve more than 500 acres of crop per day, especially for grains such as rice and corn.

References

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cc: Gary Sprock